UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,038	11/21/2005	Michael Ausborn	DV/4-32794A	1309

1095 7590 01/29/2010

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,038	AUSBORN ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-16* is/are pending in the application.

4a) Of the above claim(s) *10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 10/19/09.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwamoto et al (EP 0 761 211 hereafter '211). The claims are drawn to a microparticle comprising an active agent embedded in a biocompatible matrix and an ionic liquid.

The '211 patent teaches a microparticle comprising biocompatible polymers, ionic liquids and active agents (abstract). The biocompatible polymer is polyglycolic acid (abstract, col. 1, lin. 1-19). The ionic liquids include ammonium and pyridinium salts of ionic quaternary surfactants, including tetradecyldimethylbenzylammonium chloride (TDBAC) and cetylpyridinium chloride (CPC) (col. 2, lin. 29-40). The active agents include analgesics such as naproxen (examples 1 and 2). The particles are extruded and cut into microparticles (examples).

Regarding the process limitations recited in claim 1, it is the position of the Examiner that these limitations do not overcome the prior art as they are product by process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made

by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). As such, the prior art discloses a microparticulate formulation comprising pharmaceutically active agents embedded in a polymeric matrix, wherein the polymeric matrix is a copolymer of poly(glycolic) and lactic acid. For these reasons the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Iwamoto et al (EP 0 761 211 hereafter '211) in view of Bodmer et al (USPN 5,639,480 hereafter '480). The claims are drawn to a microparticle comprising an active agent embedded in a biocompatible matrix and an ionic liquid.

As discussed above the '211 patent discloses a microparticle formulation comprising a biocompatible polymer matrix, an active agent and an ionic surfactant. The reference is silent to the specific active agents of the instant claims, although analgesics are listed. The reference

indicates that a wide variety of active agents are usable in the formulation. The inclusion of the specific active agents of the instant claims into the microparticle formulation of the '211 would be obvious and well within the level of skill in the art. This can be seen in the '480 patent.

The '480 patent discloses a microparticle formulation comprising a biocompatible polymer such as polyglycolic lactic acid, an ionic surfactant and various active agents (col. 10, lin. 8-30). The active agents include peptides such as somatotropin or somastostatin (examples). It would have been obvious to include these peptides into the microparticle formulation of the '211 since they comprise identical carrier formulations.

Regarding the process limitations recited in claim 1, it is the position of the Examiner that these limitations do not overcome the prior art as they are product by process limitations. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983).

With these aspects in mind it would have been obvious to combine the peptide compounds of the '480 patent into the carrier microparticle formulation of the '211 patent in order to provide a stable formulation useful in treating a variety of cancers. One of ordinary skill

in the art would have been motivated to combine the prior art with an expected result of a stable cancer treatment.

Response to Arguments

Applicant's arguments filed 10/19/09 have been fully considered but they are not persuasive. Applicant argues that:

The '211 patent does not anticipate the instant claims since it does not disclose a method where an ionic liquid is removed.

The combination of the '211 and '480 patent does not obviate the instant claims since neither of the cited references recite methods of production where an ionic fluid is removed.

Regarding the first argument, it remains the position of the Examiner that the '211 patent anticipates the instant claims. As discussed above the '211 patent anticipates the product by process limitations in claim 1 by meeting the compositional components of the claim. The '211 patent discloses microparticles comprises pharmaceutically active agents embedded in a biocompatible polymer. Applicant is reminded that in product by process claims, the patentability of the claim is determined by the product and not he process of production. As such by disclosing microparticles comprising pharmaceutically active agents embedded in a biocompatible polymer the '211 patent meets the product limitations of the instant claims and thereby anticipates the instant claims. Applicant argues that the products are materially different since the '211 does not use molten salts however the molten slats are recited to be ammonium, or pyridinium salts, both of which are disclosed as useful in the invention of the '211. Applicant has not provided any evidence that the instantly claimed products are materially different from those

of the prior art due to the product by process limitations. For these reasons the claims remain anticipated.

Regarding the second argument, it remains the position of the Examiner that the combination of the '211 and the '480 patent continue to obviate the instant claims. The '211 patent discloses a microparticle comprising pharmaceutical agents embedded in a PGLA matrix. The reference is silent to the specific active agent of the instant claims, however the inclusion of these specific agents is known in microparticles comprising PGLA matrices. This can be seen in the '480 where microparticles are formed comprising PGLA matrices with somatotropin or somastostatin embedded in the polymer. The '480 patent establishes the level of skill in the art regarding the combination of microparticles comprising PGLA and somastostatin embedded in the polymeric matrix. It would have been obvious to one of ordinary skill in the art to combine the active agents into the microparticles of the '211 patent since both formulations provide microparticulate formulations useful in sustained release implant preparations. Regarding the product-by-process limitations, as discussed above these limitations do not distinguish the instant claims over the since the prior art provides a materially identical product and the patentability of product claims is dependent on the product and not the process of making. For these reasons the claims remain obviated by the combination of the '211 and '480 patents.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618